

March 20, 1998

0519 '98 MAR 23 AIO:03

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. rm.1-23
Rockville, MD 20857

Comments on this proposed FDA regulation:

The primary thrust of this proposed regulation is to address those entities and agencies which are in the business of RE-SELLING used medical devices. In pursuit of this activity, they must, to one degree or another, be considered a "manufacturer". The definition (section IV) used here for "servicers" is much too loose and should either be re-defined, or an additional definition created to define those "servicers" who are employed by the resellers / remanufacturers / rebuilders, etc. As this document is written, it will include ALL "servicers", INCLUDING those employed by the equipment's end-user owners who are only engaged in the basic maintenance of the medical device for their employers.

If this document retains the references to "servicers" as it is currently defined in this document, it will cause a great deal of additional burden on the purchasers of medical devices to attempt to comply with the additional rules, regulations, codes and standards that will result from this document. With the increasing cost of health care in the United States today, and with the thrust of the industry to attempt to control the rising cost of health care, any rules, regulations, codes or standards that might result from this document can ONLY increase the cost of health care. The Competitive Enterprise Institute puts the total regulatory burden in the U.S. in the neighborhood of \$675 billion per year, while Charles Murray and others have stated that the impact of almost all government regulatory programs is zero. Therefore we do not want to add additional unnecessary regulatory burden on health care organizations.

There are already sufficient controls provided to monitor the qualifications of "servicers" employed to maintain and repair biomedical devices after they are purchased by the end-users such as hospitals and clinics. There are already sufficient codes and standards in place to control the manufacture of medical devices. The purchasers of these devices are constrained by current codes and standards to hire only qualified technicians ("servicers"!) to maintain and repair them. The NFPA-99 standard, along with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) already provide sufficient controls on the qualifications of end-user "servicers".

971-0477

C29



ServiceMASTER

Perhaps, then, refurbishers, rebuilders, reconditioners, and "as is" remarketers of medical devices should be classified as "manufacturers". This would automatically place them under the current Good Manufacturing Practices codes and standards, along with NFPA-99 and the JCAHO. And perhaps, the term "servicers" should be removed entirely from this document.

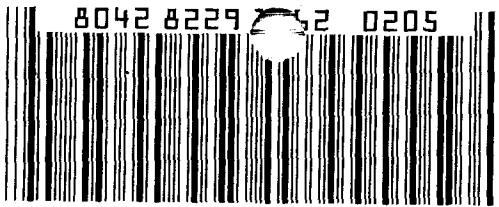
Sincerely,



Don Conrad
Director CE Development
ServiceMaster Healthcare Management Services

0518 '98 MAR 23 AM 02



FedEx**Express
Shipping
Label**☐ For use by PowerShip
Customers onlyUBFW 1/98
PART 151953 Rev. 7/97
©1994-97 Federal Express Corporation00606/01000 4454533
Sender's FedEx Account Number
0604-0158-6 8042 8229 1562**FedEx**

8042 8229 1562

FedEx Tracking Number — PULL UP PURPLE TAB

From

Ship Date

6302711300

SERVICEMASTER COMPANY I P
ONE SERVICEMASTER WAY
DOWNERS GROVE IL 60515-1700

To (If Hold for Pickup, Print FedEx Address Here) (We Cannot Deliver to P.O. Boxes or P.O. Zip Codes.)

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. Rm 1-33
Rockville, MD 20857
Release No. Phone No.

Reference Info

0009-700214-900700

**Special
Handling**☐ Hold at FedEx
Location - Weekday☐ Hold at FedEx
Location - Saturday☐ Deliver
Saturday☐ Dangerous
Goods☐ Dry
Ice

Services		FedEx Priority Overnight		FedEx Standard Overnight		FedEx 2Day		FedEx First Overnight		FedEx Express Saver		FedEx Overnight Freight		FedEx 2Day Freight		FedEx Express Saver Freight	
WEIGHT	DECLARED VALUE	<input checked="" type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box	<input type="checkbox"/> FedEx Letter	<input type="checkbox"/> FedEx Box
		<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube	<input type="checkbox"/> FedEx Pak	<input type="checkbox"/> FedEx Tube
		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.		<input type="checkbox"/> Other Pkg.	

#147924 Format# 077 G.S.I. 10/97 ::

he World On Time

N